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**PATENT, TRADEMARK, COPYRIGHT  
 AND UNFAIR COMPETITION LAW  
 AND RELATED LITIGATION**

EDMUND P. WOOD 1923-1988  
 TRUMAN A. HERRON 1935-1976  
 EDWARD B. EVANS 1936-1971

JOSEPH R. JORDAN  
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**FACSIMILE COVER SHEET**

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 Ask for sender's secretary.

TECHNICAL ADVISORS  
 HENRY M. LABODA, Ph.D.  
 LARRY D. MOORE, B.S.E.E.

TO: The Honorable Commissioner  
 Attention: Jean C. Witz  
 Art Unit 1651

FROM: Beverly A. Lyman, Ph.D.

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**CENTRAL FAX CENTER**

Fax No.: (703) 872-9306

Phone: (513) 241-2324

Date: September 4, 2003

Fax: (513) 421-7269

Pages (including cover page): 11

Re: U.S. Serial No. 09/919,102 SELECTIVE ENZYME TREATMENT OF SKIN  
 CONDITIONS  
 Attorney Docket No. HOFE-02

**ATTACHMENTS/COMMENTS: OFFICIAL**

Please deliver to Jean C. Witz

Duplicate Response to Restriction Requirement (2 pgs)

Return Postcard of Response to Restriction Requirement dated 11/4/02 (1 pg)

Copy of Response to Restriction Requirement dated 11/4/02 (4 pgs)

Copy of Reference of In re Weber, Soder, and Boksay (3 pgs)

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this correspondence is being facsimile transmitted  
 to the Patent and Trademark Office fax number (703) 872-9306 on the  
 date shown below.

*Rhonda A. Etienne*  
 Rhonda A. Etienne

September 4, 2003  
 Date

**CERTIFICATE OF FACSIMILE**

I hereby certify that this correspondence is being deposited via facsimile to The Honorable Commissioner in the United States Patent and Trademark Office, Attention: Jean C. Witz whose telephone number is (703) 308-3073 and fax number is (703) 872-9306 on September 4, 2003.

Rhonda A. Etienne 9/4/03  
Rhonda A. Etienne Date

**OFFICIAL PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Howard Fein, M.D.  
Application No.: 09/919,102  
Filed: July 31, 2001  
Art Unit: 1651  
Confirmation No.: 2446  
Examiner: Jean C. Witz  
Title: **SELECTIVE ENZYME TREATMENT OF SKIN CONDITIONS**  
Atty. Docket No.: HOFE-02

Cincinnati, OH 45202

September 4, 2003

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

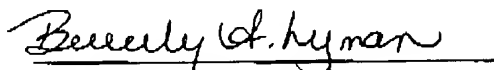
**DUPLICATE**  
**RESPONSE TO RESTRICTION REQUIREMENT**

In response to Examiner's telephone call to applicant's undersigned representative today, applicant submits 1) a duplicate of the Response to the Examiner's Restriction mailed October 2, 2002 and 2) a copy of the postcard stamped by the Patent and Trademark Office indicating receipt of applicant's response mailed November 4, 2002 timely submitted.

Applicant believes no fees are due with this submission, but authorizes  
any fees to be charged fees to Deposit Account No. 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS. L.L.P.

  
Beverly A. Lyman, Ph.D.  
Reg. No. 41,961

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K:\HOFE\02\ELECT Duplicate response.wpd

Client/Matter: HOTE-02

WIPE Docket No.: 46638

The stamp of the Patent Office hereon, may be taken as acknowledging the receipt, on the date stamped, of the following items in the captioned case:

Inventor(s): Howard Fein, M.D.

Serial No.: 09/919,102

Filing Date: July 31, 2001

Title: SELECTIVE ENZYME TREATMENT OF SKIN

Enclosures: CONDITIONS

Response to Restriction Requirement; Preliminary

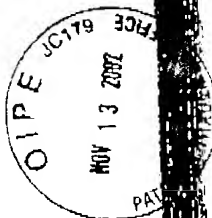
Amendment with Certificate of Mailing; and Return

Postcard

Beverly A. Lyman, Esquire

WOOD, HERRON &amp; EVANS, L.L.P.

November 4, 2002



**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on November 4, 2002.

*Kimberlee Fisher* 11/4/02  
Kimberlee Fisher Date

**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Howard Fein, M.D.  
Application No.: 09/919,102  
Filed: July 31, 2001  
Art Unit: 1651  
Confirmation No.: 2446  
Examiner: Jean C. Witz  
Title: **SELECTIVE ENZYME TREATMENT OF SKIN CONDITIONS**  
Atty. Docket No.: HOFE-02

Cincinnati, OH 45202

November 4, 2002

Commissioner for Patents  
Washington, DC 20231

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT**

In response to the Office Action mailed October 2, 2002 in the above-referenced application, applicant elects with traverse Group 1 (claims 1-10, 24-41), drawn to a method for treating a condition affecting at least one layer of the skin wherein the enzyme is trypsin.

However, applicant respectfully asserts that such a restriction is improper. Applicant has filed a Preliminary Amendment amending claims 1,2, 4-7, 9, 20, 21, 30, 34, 35, and 39-41 to recite a hydrolase. At the outset, applicant notes that amended claims 1-10 and 24-41 are now directed to methods for treating skin conditions with a composition that contains a hydrolase. Amended claims 11-20 (Group II) and amended claims 21-25 (Group III) are directed to a composition that contains various hydrolases, and claims to such compositions should not be restricted based on enzyme function. Applicant now provides the following analysis in support of his assertion regarding the impropriety of a species election.

First, the Examiner's restriction forces applicant to fragment the invention claimed within a single claim. Under *In re Weber, Soder, & Boksay*, 198 U.S.P.Q. 328, 331-32 (C.C.P.A. 1978) (copy attached) this is not permitted.

The invention in *Weber* related to cyclic diamine derivatives possessing a common psychotherapeutic property and was identified by a single generic formula expressed in Markush format. The instant invention relates to hydrolases, a class of transferases, possessing the common biochemical property of transferring a donor group to water. The hydrolases are expressed in Markush format; the selection of which hydrolase to use in the composition and method of treatment depends upon the layer or layers of skin to be treated.

In *Weber*, the court viewed the Examiner's restriction as tantamount to a refusal to examine. It held that the United States Patent and Trademark Office has the authority to restrict between claims of an application reciting one or more independent and

distinct inventions, but does not have the authority to require an applicant to divide up a single claim and present it in different applications; this would allow an Examiner, rather than an applicant, to define an invention in violation of 35 U.S.C. §121, ¶2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention", emphasis added). Weber at 332. While recognizing the need for efficiency in limiting each application to one invention, the court stated that

...in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights [of the applicant] are paramount.

Second, §803.02 of the MPEP states that if the claims have unity of invention, it is improper to refuse to examine "that which applicants regard as their invention". Unity of invention exists where compounds included within a Markush group share a common utility and share a substantial structural feature as being essential to that utility.

With regard to the instant application, all of the method and composition claims as amended share a common class of enzyme, that is, the hydrolases, which have the same utility to transfer a donor group to water.

Applicant also respectfully disagrees with the Examiner's position that "in the instant case the method can be practiced with a materially different product such as an alpha-hydroxy acid." Alpha-hydroxy acids are conventionally used in over-the-counter cosmetics to cause nonspecific exfoliation or shedding of the skin surface. When these

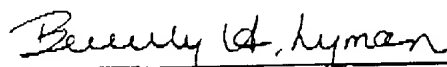
acids are used in higher concentrations than what is conventionally used in exfoliation cosmetics, they can cause nonspecific tissue damage such as the detachment of keratinocytes and epidermolysis. In applicant's instant applications, the hydrolases used in the composition and method produce selective tissue destruction limited to one or more layers of the skin that are involved with a certain skin condition.

For the reasons discussed, applicant respectfully requests that the Examiner reconsider the restriction requirement.

Applicant knows of no fee due with this submission, as November 2, 2002 was a Saturday. However, if any fees are necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to Deposit Account 23-3000.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.



Beverly A. Lyman, Ph.D.

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